



Laboratory Standard Operating Procedure for:

# Tamoxifen

***Principal Investigator (PI) Approval is Required Prior to Performing this Procedure***

## Description

*This standard operating procedure outlines the handling and use of tamoxifen. Review this document and supply the information required in order to make it specific to your facility. In accordance with this document, laboratories should use appropriate controls, personal protective equipment, and disposal techniques when handling tamoxifen.*

Tamoxifen is classified as a hazardous drug according to the National Institute for Occupational Safety and Health (NIOSH). Tamoxifen is a triphenyl ethylene derivative with marked anti-estrogen properties, which binds to estrogen receptors and, as a result, has proven useful in the treatment of breast cancer (antineoplastic). Tamoxifen citrate has been used to stimulate ovulation in infertility.

Synonyms: Nolvadex, Istubal, Valodex

## Potential Hazards

- May cause cancer.
- May impair fertility and cause harm to the unborn child or breastfed babies.
- Accidental ingestion of the material may be harmful.
- May cause eye irritation.
- This product may be harmful if inhaled and cause respiratory tract irritation. Persons with impaired respiratory function, airway diseases, and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.
- The material is not thought to be a skin irritant (as classified using animal models). But may be harmful if absorbed through the skin and may cause skin irritation; systemic effects may result following absorption. Entry into the blood-stream through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

## Engineering Controls

- Use a biological safety cabinet or chemical fume hood during reconstitution and dilution of this material.
- Syringes used for tamoxifen injection must be safety engineered (self-sheathing syringes, luer-lock syringes, etc.)
- Use with animals typically requires ABSL2 containment housing.
- Animals should be appropriately restrained and/or sedated prior to administering injections and other dosing methods.
- Laboratories and other spaces where handling of tamoxifen occurs must be equipped with an eyewash station.

## Work Practice Controls

- Avoid inhalation.
- Good hygiene practice requires that exposure be kept to a minimum and that suitable PPE and control measures be used in an occupational setting.
- Decontamination should consist of surface cleaning with water and detergent followed by thorough rinsing. The use of detergent is recommended because there is no single accepted method of chemical deactivation for all agents involved.
- A plastic backed absorbent pad should be placed under the work area during the process. This should be changed at the end of each procedure or when a spill occurs.

### **Personal Protective Equipment (PPE)**

Appropriate lab attire including long pants and closed toe shoes must be worn. Personal protective equipment includes a lab coat or disposable coveralls, eye protection and two pairs of disposable nitrile gloves. Gloves should be changed frequently and should be pulled up over sleeves if possible to reduce the likelihood of any exposed skin. Wash hands and arms immediately after working with the substance.

Note: Respirators are masks designed to protect the wearer from specific airborne hazards and are different from surgical masks, which protect the wearer only from splashes and are primarily intended to protect others from infectious aerosols exhaled by the wearer. Respirator use requires employee participation in the Respiratory Protection Program, which involves medical clearance and annual fit testing and training. Please be clear about use of surgical masks versus respirators. (Do NOT use the vague term “masks”.)

### **Transportation and Storage**

- Keep containers tightly closed and in dry, well-ventilated area.
- Keep away from light.
- Avoid strong oxidizing agents.
- Tamoxifen is regulated by DOT as a Hazardous Material as well as IATA for Transport of Dangerous Goods.

### **Waste Disposal**

All hazardous chemical waste should be placed in an appropriate container for disposal (pail or bottle). The container should be closed except when actively adding waste. The container must be located in the area where hazardous drugs are being used.

All items contaminated by hazardous drugs, including gloves, syringes, vials needles, animal bedding and solution containers should be disposed according to EHS guidelines.

- Sharps – place needles, syringes with needles attached and other breakable items into appropriately labeled sharps containers.
- Empty stock vials, reagent bottles, etc. – triple rinse with copious amounts of water. Deface label with black magic marker or scraper. Place in a cardboard box for disposal.

Because most spent, unused and expired chemicals/materials are considered hazardous wastes, they must be properly disposed of. ***Do not dispose of chemical wastes by dumping them down a sink, flushing in a toilet or discarding in regular trash containers.*** Contact EHS at (313) 593-0921 for waste containers, labels, manifests, waste collection and for any questions regarding proper waste disposal. Also refer to EHS’s [Hazardous Waste webpage](#) for more information.

### **Exposures/Unintended Contact**



***If the employee is in need of emergency medical attention, call 911 immediately.***



#### **SWALLOWED**

- Rinse mouth with water.
- Consult a physician.

#### **EYE**

If this product comes in contact with the eyes:

- Wash out immediately with fresh running water for a minimum of 15 minutes.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- If pain persists or recurs seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

#### **SKIN**

If skin contact occurs:

- Immediately remove all contaminated clothing, including footwear.
- Flush skin and hair with running water (and soap if available) for a minimum of 15 minutes.
- Seek medical attention in event of irritation.

#### **INHALED**

- Move person from contaminated area into fresh air.
- Move person into fresh air.
- Seek medical attention.

Contact EHS for advice on symptoms of chemical exposure, or assistance in performing an exposure assessment.

Report all work related accidents, injuries, illnesses or exposures to WorkConnections within 24 hours by completing and submitting the [Illness and Injury Report Form](#). Follow the directions on the WorkConnections website [Forms Instructions](#) to obtain proper medical treatment and follow-up.

Complete the [EHS Laboratory Incident and Near-Miss Report](#) form.

#### **TREATMENT FACILITIES:**

##### **Midwest Medical Center -- *Campus Employees (including student employees)***

Mon-Fri 7:30 am - 4:30 pm  
9301 Middlebelt Road  
Romulus, MI 48174  
Phone: 734-941-1000

After hours - go to:

##### **Midwest Medical Center**

Open 24/7  
4700 Schaefer  
Dearborn, MI 48126  
Phone: 313-581-2600

**Henry Ford Medical Center-Fairlane -- *University students (non-life threatening conditions)***

19401 Hubbard Drive

Dearborn, MI 48126

Phone: 313-928-8278

Click [here](#) for more information.

### **Spill Procedure**

- When a spill occurs, ***personal safety should always come first.***
- Alert and clear everyone in the immediate area where the spill occurred.

A **minor (small) chemical spill** is one that the laboratory staff is capable of handling safely without the assistance of safety and emergency personnel, i.e., (*less than 1 Gallon or 3.5 Liters*). A **major/large chemical spill** requires active assistance from emergency personnel.

### **Spill Response Steps:**

#### **MINOR CHEMICAL SPILL**

- Alert people in immediate area of spill.
- Open outside windows, if possible.
- Use proper personal protective equipment (PPE) as indicated above.
- Avoid breathing vapors from spill.
- Confine spill to as small an area as possible.
- **Do not wash spill down the drain.**
- Use appropriate spill kits/sorbents to absorb spill. Collect contaminated materials and residues and place in container. For powdered chemicals sweep carefully to avoid generation of dust or, if appropriate, use moist sorbent pads or wet the powder with a suitable solvent and then wipe with a dry cloth. Contact EHS at (313) 593-0921 for proper disposal.
- Clean spill area with water.

#### **MAJOR CHEMICAL SPILL**

Report large chemical spills (*greater than 1 Gallon or 3.5 Liters*) in corridors or common areas, e.g., hallways, elevators, eating areas, rest rooms, offices, etc., to Public Safety at 911.

- Attend to injured or contaminated persons and remove them from exposure.
- Alert people in the laboratory to evacuate.
- **Call Public Safety at (313) 593-5333 or (911 from a campus phone) immediately for assistance.**
- Close doors to affected area.
- Post warnings to keep people from entering the area.
- Have person available that has knowledge of incident and laboratory to assist emergency personnel.

### **Additional Spill Links:**

- [Chemical Spill Control Information](#)

Report all emergencies, suspicious activity, injuries, spills, and fires to Public Safety by calling at (313) 593-5333 or 911 from a campus phone. Register with the University of Michigan-Dearborn [Emergency Alert System](#).

### Training of personnel

All person are required to attend initial (first-time) training in class (go to <http://www.umd.umich.edu/training/> to register). Refresher training can be completed via [MyLINC](#), the **Comprehensive Laboratory Safety** session (BLS009 or equivalent). Furthermore, all personnel shall read and fully adhere to this SOP when handling tamoxifen.

### Certification

I have read and understand the above SOP. I agree to contact my Supervisor or Lab manager if I plan to modify this procedure.

Name	Signature	UM ID #	Date

Principal Investigator \_\_\_\_\_

Revision Date \_\_\_\_\_